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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,340	02/19/2002	Hidekazu Shodai	YAM 2 0009	3665

7590 01/31/2008
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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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01/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/914,340

Applicant(s)

SHODAI ET AL.

Examiner

Susan T. Tran

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8 and 10-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 10-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1, 7, 12-17, 19-24 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 and Brox US 4,780,316.

Ebert teaches a chewable soft gelatin capsule comprising confectionary fill material (abstract; and page 2, lines 40-47). The filled capsule is dried over a length of time until the desired chewing characteristics are attained (abstract; page 2, last paragraph; and examples). The capsule shell comprises gelatin, and plasticizer such as glycerin or sorbitol (page 1, last paragraph through page 2, paragraphs 1-5). The shell further comprises flavoring agent, and taste modifier (page 2, lines 33-35).

Ebert does not explicitly teach the claimed confectionary fill material.

Monte teaches a confectionary composition useful for the delivery of active agents, the composition comprising chocolate candy consisting mainly of roasted cacao beans, cacao butter, and sugar (abstract; column 5, lines 66 through column 6, lines 1-9; and example 29). Monte further teaches active agents include vitamins, enzymes, phytochemicals, and alimentary vegetable compositions are incorporated in the confection core (column 5, lines 30-35; and example 29). Thus, it would have been obvious to one of ordinary skill in the art to modify the chewable soft capsule of Ebert to include the confectionary composition of Monte to obtain the claimed invention, because Monte teaches using chewable confectionary composition as a carrier for drugs, because Monte teaches chewable confectionary such as chocolate candy is known in

pharmaceutical art, and because Ebert teaches the use of confectionary composition as a fill material suitable for the delivery of active agents.

It is noted that Ebert does not expressly teach the claimed drying temperature. However, absent of evidence to the contrary, the burden is shifted to applicant to show that Ebert does not teach dry the capsule under the claimed temperature. This is because Ebert teaches drying the soft gelatin capsule to obtain characteristics. It is noted that Ebert teaches an improved chewable soft gelatin capsule having the properties desired by the applicant, *e.g.*, normal chewing consistency over an extended period of time (page 1, lines 35-37), and avoidance of unpleasant taste (page 1, 2nd paragraph). However, to be more specific, Brox is cited for the teaching of storing (aging) soft gelatin capsule under temperature of 20°C, 30°C, and 40°C for one month to obtain a chewable capsule having suitable hardness (abstract; and column 5, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art to age the soft capsule of Ebert at 30°C and 40°C in view of the teaching of Brox, because Brox teaches that it is well known to store soft gelatin capsule under such temperature to achieve suitable capsule shell hardness, and because Ebert teaches the desirability to obtain soft gelatin capsule having improved characteristics.

Claims 1, 4-7, 11, 12, 15-17 and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Cavanak US 5,639,724 and Brox US 4,780,316.

Ebert and Brox are relied upon for the reason stated above. Ebert does not explicitly teach the claimed filling material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Ebert to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches incorporating drug into chocolate base is known in pharmaceutical art, because Cavanak teaches a chocolate candy comprising cyclosporin to achieve acceptable taste (column 3, lines 41-45), and because Ebert teaches the use of confectionary as a fill material suitable for the delivery of a wide variety of drugs.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ebert et al. GB 2151201 A, in view of Monte US 5,578,336 or Cavanak US 5,639,724, and Nishizawa et al. US 4,463,024.

Ebert in view of Monte or Cavanak are relied upon for the reasons stated above. Monte and Cavanak do not teach bitter chocolate.

Nishizawa teaches a flavoring composition comprising chocolate including bitter chocolate (example 18). Thus, it would have been obvious to one of ordinary skill in the art to include bitter chocolate to the chocolate composition of Monte or Cavanak to

obtain the in view of the teaching of Nishizawa, because Nishizawa teaches using bitter chocolate from cacao bean to obtain a superior flavoring composition, because Monte and Cavanak teaches the use of chocolate including cacao bean.

Claims 1, 4-7, 11, 12, 15-17, 19, 20, 22 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724.

Lech teaches a chewable soft gelatin capsule comprising a solid or liquid fill material (abstract; and column 2, lines 48-50). The fill material comprises flavors, sweeteners, and other food-grade excipient including oils and fats fillers (column 3, lines 1-4; and column 4, lines 66 through column 5, lines 1-17). Lech further teaches the filled capsule is stored at temperature 30°C, 40°C and 50°C for an extended period of time (aging) (column 7, lines 28-30).

Lech does not expressly teach the claimed fill material.

Cavanak teaches a confectionary composition comprising vegetable fats, and a drug such as cyclosporin (abstract; column 13, lines 7-26; and example 5). Vegetable fats include cacao fat, cacao butter, conventional chocolate bases, couverture chocolate, and mixtures thereof (ID). Example 5 discloses the claimed percent amounts of chocolate in the composition. Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule of Lech to include the chocolate-cyclosporin candy in view of the teaching of Cavanak, because Cavanak teaches it is well known in pharmaceutical art to use vegetable fat including chocolate base as a fill material for oral dosage form, (column 3, lines 41-45), and because Lech teaches the desirability to

use fill materials comprise flavors, sweeteners, and fats to obtain a suitable oral dosage form.

Claims 8, 12-16 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech US 6,027,746, in view of Cavanak US 5,639,724 and Katsuragi et al. US 5,756,543.

Lech and Cavanak are relied upon for the reason stated above. Lech does not teach fats include lard, coconut oil, or polyethylene glycol.

Katsuragi teaches a bitterness-relieving agent comprising fats including vegetable and animal fats such as coconut oil, lard, and the like, and combination thereof (abstract; and column 4, lines 12-30). Thus, it would have been obvious to one of ordinary skill in the art to modify the capsule fill of Lech to include coconut oil, lard, and polyethylene glycol as a fat in view of the teaching of Katsuragi, because Katsuragi teaches the use of these fats in a composition to mask the taste of bitter drugs, and because Lech teaches the desirability to use fat as a fill material to obtain a suitable chewable capsule in which the bitter taste of drug has been masked.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lech in view of Mehta US 5,084,278.

Lech is relied upon for the reason stated above. Lech does not explicitly teach the flavoring agent such as chocolate flavor.

Mehta teaches a chewable taste mask capsule comprising a fill composition containing sweetening agent, and flavoring agent includes chocolate flavor (column 9,

lines 46 through column 10, lines 1-15). Thus, it would have been obvious for one of ordinary skill in the art to include chocolate flavor in the fill material of Lech, because Mehta teaches the use chocolate flavor in chewable dosage form is preferable, and because Lech teaches the desirability to include a wide variety of flavors useful to obtain a chewable dosage form.

Response to Arguments

Applicant's arguments filed 11/14/07 have been fully considered but they are not persuasive.

Applicant indicates that the cited Ebert GB 2151201 in this office action appears substantially similar to Ebert 4,532,126, but requests the office to explain why GB 2151201 is cited instead of Ebert 4,532,126.

In response to applicant's argument, it is noted that the RCE filed in 03/26/07 amending the claims to include "chewable capsule", which necessitated the new search and application of new prior arts. Further, as indicated by the applicant, the references appear substantially similar, the examiner is unable to understand why it matters if the GB 201 is cited instead of the US 126.

Applicant argues that Ebert in view of Monte and Brox do not teach all features of the present claims. Applicants note that Ebert merely discloses drying. Ebert does not inherently or explicitly teach the claimed drying temperature (30 - 40°C) or the claimed drying time (5 hours or more). For example, one may dry at higher temperatures for short periods of time. In other words, Ebert does not teach or suggest these claim

features at all. In addition, the drying temperature and time are critical to the formation of V-type crystal in the fill material. This criticality rebuts any suggestion that the claimed drying temperatures and times are obvious.

In response to applicant's arguments against Ebert individually, one cannot show nonobviousness by attacking reference individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Further, in response to applicant's argument that "*the drying temperature and time are critical to the formation of V-type crystal in the fill material*", it is noted that the present claims do not recite the temperature and time that are indicated "critical". The claims recite aging temperature of 30-40°C. However, the present specification clearly shows that hardness immediately falls right after 35°C (at higher temperatures). The specification discloses that V-type crystal cacao butter is subjected to aging at 35°C for 16 hours (page 37, 2nd paragraph; page 38, 1st paragraph; Fig. 2 and Fig. 4). Accordingly, it appears that limitations beyond 35°C and 16 hours do not result in unexpected results.

Applicant argues that the Examiner cited Brox as teaching the storage of soft gelatin capsules under temperatures of 20°C, 30°C, and 40°C for one month as being equivalent to the aging step and as teaching that it is well known to store soft gelatin capsules under such temperatures to achieve suitable capsule shell hardness. In response, Applicants submit that Brox does not teach that storage is equivalent to aging nor that one should store capsules at such temperatures to achieve capsule shell hardness. Brox is concerned with the fact that when liquid polyethylene glycol is used

as a fill, it absorbs water from the shell and makes the shell brittle. See Column 1, lines 22-42. Brox discloses a method for solving this disadvantage by providing a shell containing sorbitol. Brox then tests the new composition to ensure that the capsules are not embrittled. As a proxy, Brox tests the hardness of the samples. Brox does not store the soft gelatin capsule in order to achieve suitable capsule shell hardness. Thus, the motivation to store the capsule at a temperature of 30-40°C for more than 5 hours is not present. One of ordinary skill in the art, looking for a drying time and temperature with which to modify Ebert, would not look to test conditions for storage to find drying times and temperatures. Applicants also note that the soft capsule of the instant claims does not necessarily have the same shell brittleness problems that Brox had, so there is no motivation to solve the same problem that Brox had in Ebert. Thus, there is no motivation to combine the references. Applicants request withdrawal of the § 103(a) rejection based on Ebert, Monte, and Brox.

In response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Brox is cited solely for the showing that regular storage temperature falls within the claimed aging temperature. Thus, the burden is shifted to applicant to show that Ebert does not dry the obtained capsule at the claimed aging temperature. Further, it is noted that the rejected claims are directed

to composition claims. The aging step is future intended use, part of the product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The examiner notes the comparison data showing in the present specification. However, the examiner is unable to determine the unexpected result because the difference of the improved product is only recognized by 0.2 percent of the population. See for example Fig. 4, out of 5 volunteers, 4.8 compared to 5 report unpleasant sensation from the shell; 4.4 compared to 4.6 report bitterness of fill material; 4.6 compared to 4.8 report total sensation of ingestion and usability. According to the data, it appears that no significant improvement has been shown.

Applicant argues that there is no motivation to combine Ebert in view of Cavanak and Brox. In particular, there is no motivation to combine Ebert and Brox, as discussed above. Cavanak is used only to teach the fill material and does not remedy the deficiencies in Ebert and Brox. Applicants request withdrawal of the § 103(a) rejection.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the

references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the reason for the combination of Brox and Ebert is discussed above. Cavanak is cited solely for the teaching of using chocolate base in pharmaceutical fill to achieve acceptable taste (column 3, lines 41-45).

Applicant argues that there is no motivation to combine Lech and Cavanak. In particular, Lech merely discloses that his capsules, when tested with a fill material that was not cacao butter, were stable for extended periods at room temperature, 30°C, 40°C, and 50°C. However, this disclosure only shows that the capsules can be stored at such temperatures. Lech does not suggest a reason why they should be stored at such temperatures. Because Lech does not provide this reason, Applicants submit that, in the words of § 2143.01, the references do not suggest the desirability of the instant claims. There is no indication that storage at high temperatures is desired and Applicants submit that the coincidental overlap of the tested storage temperatures with the claimed drying temperature is simply that, coincidence. Coincidence cannot be considered motivation. Applicants traverse the rejection.

However, in response to applicant's argument that *Lech does not teach a reason why they should be stored at such temperatures, and that Lech does not teach the desirability of the instant claims*, it is noted that no where in the present claims recite any reason why the claimed capsule has to be aged at certain temperature. Further, the rejected claims are directed to composition claims. The aging step is future

intended use, part of the product-by-process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The comparison data in the present specification does not appear to present any unexpected result over the claimed aging parameters. Moreover, from the data shows in Fig. 4, it appears that the improved product results in an even more unpleasant sensation from the shell, as well as more bitterness of fill material. Is this the desirability of the present invention?

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SUSAN TRAN
PRIMARY EXAMINER